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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,558	06/17/2005	Yitzchak Hillman	HILLMAN 1	9264

1444 7590 12/07/2007

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,558	HILLMAN, YITZCHAK	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-108 and 113-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *100-108 and 113-125* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of record for this application has changed. Upon further consideration, the previous restriction requirement, mailed August 8, 2007, is withdrawn in favor of the instant requirement, set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 107 and 108, drawn to an article of manufacture comprising a molecule capable of binding AMP and/or AMP-like molecule.

Group II, claim(s) 107, drawn to an article of manufacture comprising an enzyme capable of cleaving AMP and/or AMP-like molecule.

Group III, claim(s) 107, drawn to article of manufacture comprising an siRNA molecule capable of inducing degradation of an mRNA encoding AMP and/or AMP-like molecule.

Group IV, claim(s) 107, drawn to an article of manufacture comprising a DNAzyme capable of cleaving an mRNA or DNA encoding AMP and/or AMP-like molecule.

Group V, claim(s) 107, drawn to an article of manufacture comprising an antisense polynucleotide capable of hybridizing with mRNA encoding AMP and/or AMP-like molecule.

Group VI, claim(s) 107, drawn to an article of manufacture comprising a ribozymes capable of cleaving an mRNA encoding AMP and/or AMP-like molecule.

Group VII, claim(s) 107, drawn to an article of manufacture comprising a non-functional analog of at least a functional portion of AMP and/or AMP-like molecule.

Group VIII, claim(s) 107, drawn to an article of manufacture comprising a molecule capable of inhibiting activation or ligand binding of AMP and/or AMP-like molecule.

Group IX, claim(s) 107, drawn to an article of manufacture comprising a triplex-forming oligonucleotide capable of hybridizing with a DNA encoding AMP and/or AMP-like molecule.

Group X, claim(s) 118-121, drawn to an article of manufacture comprising an AMP and/or AMP-like molecule.

Group XI, claim(s) 101 and 102, drawn to a method of treating a disease in a subject via providing a molecule capable of binding AMP and/or AMP-like molecule.

Group XII, claim(s) 101, drawn to a method of treating a disease in a subject via providing an enzyme capable of cleaving AMP and/or AMP-like molecule.

Group XIII, claim(s) 101, drawn to article of manufacture comprising an siRNA molecule capable of inducing degradation of an mRNA encoding AMP and/or AMP-like molecule.

Group XIV, claim(s) 101, drawn to a method of treating a disease in a subject via providing a DNAzyme capable of cleaving an mRNA or DNA encoding AMP and/or AMP-like molecule.

Group XV, claim(s) 101, drawn to a method of treating a disease in a subject via providing an antisense polynucleotide capable of hybridizing with mRNA encoding AMP and/or AMP-like molecule.

Group XVI, claim(s) 101, drawn to a method of treating a disease in a subject via providing a ribozymes capable of cleaving an mRNA encoding AMP and/or AMP-like molecule.

Group XVII, claim(s) 101, drawn to a method of treating a disease in a subject via providing a non-functional analog of at least a functional portion of AMP and/or AMP-like molecule.

Group XVIII, claim(s) 101, drawn to a method of treating a disease in a subject via providing a molecule capable of inhibiting activation or ligand binding of AMP and/or AMP-like molecule.

Group XIX, claim(s) 101, drawn to a method of treating a disease in a subject via providing a triplex-forming oligonucleotide capable of hybridizing with a DNA encoding AMP and/or AMP-like molecule.

Group XX, claim(s) 113-117 and 122-125, drawn to a method of treating a disease in a subject via providing an AMP and/or AMP-like molecule.

Claim 106 link(s) inventions I-X. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 106.

Claim 100 and 103-105 link(s) inventions XI-XX. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 100.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art. The technical feature, an AMP/AMP-like compound, e.g. β-defensin, is not a contribution over the art, as MORRISON (G. Morrison et al. Infect. Immun. (2002) 70(6), pages 3053-3060) teaches β-defensin-1 and -2

in saline (e.g. *Functional analysis...*, page 3055), and thus the claims lack unity, as the β-defensin (an AMP and/or AMP-like molecule) inherently must function to decrease the activity and/or level of AMP and/or AMP-like molecule as indicated in Applicant's response (10/9/07, page 5). Additionally the instructions do not distinguish the product from the prior art. ("Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art." *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 100-105, 113-117, 122, 124 and 125 are generic to a plurality of diseases, including arthritis, as recited in claim 123, and the myriad of diseases disclosed in the specification, too numerous to recite individually, not limited to those recited on page 69 and 70.

Claims 106, 107 and 113-125 are generic to the AMP/AMP-like molecule, including the species LL-37, FALL-39 (claim 125), β-defensin-1 and β-defensin-2 (e.g. claim 120).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As indicated above, with regards to the articles of manufacture, Morrison teaches β-defensin-1 and -2 in pharmaceutical compositions, and thus the technical feature is not a contribution over the art and the species lack unity.

With regards to the diseases, each disease is distinct one from another such that the technical feature of each is the unique patient population, etiology and pathology of the disease, wherein the technical feature is not shared by another patient population and thus the species lack unity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

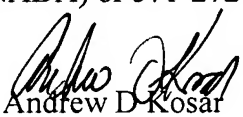
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew D. Kosar
Patent Examiner
Art Unit 1654